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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: RUDDY et al.

Serial No.: 08/852,495

Filed: May 7, 1997

For: POLYMORPHISMS IN THE REGION  
OF THE HUMAN HEMOCHROMATOSIS  
GENE

Confirmation No.:

Group Art Unit: 1644

Examiner: DECLoux, A.

Attorney Docket No.: 8907-057-999

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### INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

- 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
- 1b. A legible copy of :
  - ☒ Each U.S. patent application publication and U.S. and foreign patent;
  - ☒ Each publication or that portion which caused it to be listed on the PTO-1449;
  - ☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
  - ☐ all other information or portion which caused it to be listed on the PTO-1449.
- 1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
- 1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.

2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):

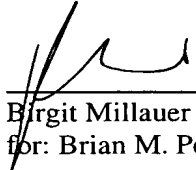
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
  - ☐ Before the mailing of the first Office action on the merits;
  - ☒ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.
- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
  - ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.
4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.
- The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:
- ☐ enclosed.
  - ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.
- The Certification Statement in Item 5 below is applicable.
5. ☐ Certification Statement (*applicable if Item 3a or Item 4 is checked*)
- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. \_\_, filed on \_\_, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. \_\_, filed on \_\_, and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (*Check either Item 7a or 7b*)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on \_\_\_\_\_. A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on \_\_\_\_\_.
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date November 18, 2002

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for: Brian M. Poissant (Reg. No. 28,462)

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## LIST OF REFERENCES CITED BY APPLICANT

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## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,399,216	Aug. 1983	Axel et al.			
	AB	4,434,156	Feb. 1984	Trowbridge			
	AC	4,666,927	May. 1987	Hider et al.			
	AD	4,683,202	Jul. 1987	Mullis			
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	AP	5,424,057	Jun. 1995	Peter et al.			
	AQ	6,025,130	Feb. 2000	Thomas et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AR	CA 2115222	Aug. 1994	CA				
	AS	CA 2115221	Aug. 1994	CA				
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	AU	EP 0 315 434	May. 1989	EP				
	AV	EP 0 346 281	Dec. 1989	EP			X Abstract	
	AW	DE 208 609	Apr. 1984	DE				X

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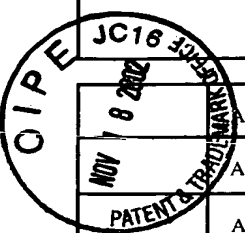
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BI	Calandro, L.M., et al., "Characterization of a Recombinant That Locates the Hereditary Hemochromatosis Gene Telomeric to HLA-F," Hum. Genet. (1995) 96:339-342 (Kaiser Foundation Research Institute).						
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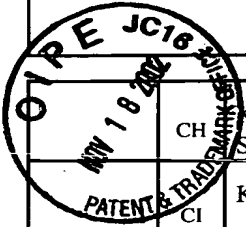
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CI	Kramer, M.F., et al., "The Polymerase Chain Reaction," Current Protocols in Molecular Biology (1993) Chapter 15 pp. 15.0.1-15.1.14 (ISBN 0-471-30661-4).
CJ	Lemarchand, P., et al., "Adenovirus-Mediated Transfer of a Recombinant Human $\alpha_1$ -Antitrypsin cDNA to Human Endothelial Cells," Proc. Natl. Acad. Sci. USA (1992) 89:6482-6486 (National Institutes of Health).
CK	Lin, A.Y., et al., "Expression of T Cell Antigen Receptor Heterodimers in a Lipid-Linked Form," Science (1990) 249:677-679 (Stanford Univ. School of Medicine).
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CO	Mulford, C.A., et al., "Endocytosis of the Transferrin Receptor is Altered During Differentiation of Murine Erythroleukemic Cells," J. Biol. Chem. (1988) 263(11):5455-5461 (National Institutes of Health).
CP	Murray, J.C., et al., "A Comprehensive Human Linkage Map with Centimorgan Density," Science (1994) 265:2049-2054 (Univ. of Iowa).
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CT	Orphanos, V., et al., "Thirteen Dinucleotide Repeat Polymorphisms on Chromosome 6," Hum. Mol. Genet. (1993) 2(12):2196 (Cancer Genetics).
CU	Patterson, M., et al., "Molecular Characterization of Cell Cycle Gene CDC7 From Saccharomyces Cerevisiae," Mol. Cell Biol. (1986) 6(5):1590-1598 (0270-7306/86).
CV	Raha-Chowdhury, R., et al., "Allelic Associations and Homozygosity at Loci from HLA-B to D6S299 in Genetic Haemochromatosis," J. Med. Genet. (1995) 32:446-452 (Univ. of Wales College of Medicine).
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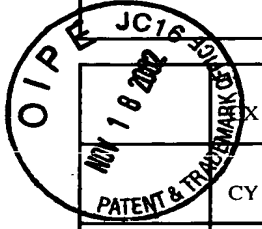
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| DB | Sood, A. K., et al., "Isolation and Partial Nucleotide Sequence of a cDNA Clone for Human Histocompatibility Antigen HLA-B by Use of an Oligodeoxynucleotide Primer," Proc. Natl. Acad. Sci. USA (1981) 78(1):616-620 (National Institutes of Health).                        |
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| DD | Totaro, A., et al., "New Polymorphisms and Markers in the HLA Class I Region: Relevance to Hereditary Hemochromatosis (HFE)," Hum. Genet. (1995) 95:429-434 (Italian Ministry of Health).   |
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| DF | Weber, J.L., et al., "Dinucleotide Repeat Polymorphism at the D6S105 Locus," Nucl. Acids Res. (1991) 19(4):968 (National Institutes of Health).   |
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| DH | Zijlstra, M., et al., " $\beta$ 2-Microglobulin Deficient Mice Lack CD4 <sup>+</sup> 8 <sup>+</sup> Cytolytic T Cells," Nature (1990) 344:742-746 (Cancer Research Institute).  |
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